

FDA Action Plan for Acrylamide Activities and Progress

**Terry Troxell, Ph.D.
Lauren Posnick, Sc.D.
FDA**

May 12, 2003

OEHHA Public Workshop on Acrylamide



Today's Goal



- **The purpose of this talk is to review FDA plans and activities on acrylamide.**
- **FDA is not recommending any position on the California state issue of Proposition 65 and acrylamide.**



Overview

- **Background on acrylamide**
- **FDA Action Plan**
- **FDA survey, formation, and exposure data**



Background

- **April 24, 2002—Swedish scientists report finding acrylamide in food, sparking international concern.**
- **Acrylamide has a long history of use for industrial purposes.**
- **Now acrylamide appears to form in certain foods as a result of cooking, particularly carbohydrate-rich foods.**



Reaction mechanism

- Major reaction mechanism identified by September 2002 by four research groups
- Amino acid asparagine reacts with sugars (like glucose) under appropriate temperature conditions to form acrylamide.



Why is acrylamide in food a concern?

- **Known neurotoxicant**
- **Potential carcinogen**
- **High levels in food compared with other cooking related carcinogens**



What makes acrylamide in food a complex issue?

- **Found in a wide range of foods, including staples of our diet**
- **Formed through traditional cooking practices**
- **Formed during food processing and at home**
- **Related to flavor-producing Maillard reactions**
- **Formed from nutrients in food**



FDA Response to Acrylamide: Overview



- **Developed an Action Plan for acrylamide**
- **Developed method to test for acrylamide in food**
- **Tested a wide variety of foods**
- **Prepared exposure assessment**
- **Laid out plans for needed toxicology research**



FDA Response to Acrylamide: Overview

- **Conducting formation research and encouraging research by industry and academia**
- **Ultimate goal—a risk assessment incorporating new data that will provide scientific basis for appropriate risk management**



Action Plan

- **The Action Plan outlines FDA's goals and planned actions on acrylamide in food over the next several years.**
- **FDA presented the Draft Action Plan at a public meeting in September and a Food Advisory Committee subcommittee meeting in December.**
- **We revised the plan and presented it to the full Food Advisory Committee in February.**
- **We are now finalizing the Action Plan in light of the Committee recommendations.**



Action Plan: Overall Goal



Through scientific investigation and risk management decision making, prevent and/or reduce potential risk of acrylamide in foods to the greatest extent feasible.



Action Plan: Major goals

- **Develop rapid or inexpensive screening methods and validate confirmatory methods of analysis.**
- **Identify mechanisms responsible for the formation of acrylamide in foods and identify means to reduce acrylamide exposure.**



Action Plan: Major goals

- **Assess the dietary exposure of U.S. consumers to acrylamide by measuring acrylamide levels in various foods and estimating dietary exposure.**



Action Plan: Major goals

- **Characterize the potential risks and uncertainties associated with exposure to acrylamide in foods by assessing the available information, by expanding research into acrylamide toxicology to reduce uncertainty, and by performing a quantitative risk assessment with the new information.**



Action Plan: Major goals

- **Develop and foster public/private partnerships to gather scientific and technological information and data for assessing the human risk.**
- **Inform and educate consumers and processors about the potential risks associated with acrylamide throughout the assessment process and as knowledge is gained.**



Action Plan: Major goals

- **Provide all the essential elements for risk analysis, i.e., risk assessment, risk communication, and risk management.**



Specific Action Areas

- **Methodologies**
- **Research on Formation**
- **Measuring Exposure**
- **Toxicology and Health Effects**
- **Epidemiology**
- **Risk Assessment**
- **Meetings**
- **Inform and Educate the Public**
- **Further Actions**



Action highlights

Measuring exposure

- **CFSAN method—June 2002 posting and two revisions—seeking AOAC validation**
- **Retail foods, gathered locally and nationally**
- **Total Diet Study foods**
- **Further testing as needed**
- **WHO/FAO Acrylamide Infonet data on U.S. levels**



Action highlights

Toxicology studies

- **Bioavailability**
 - **Food versus water**
- **High-dose vs very low-dose exposures**
 - **High-dose: P450 metabolism to carcinogen glycidamide**
 - **Low dose: less glycidamide formed?**



Action highlights



Toxicology studies

- **Adducts**
 - **Hemoglobin adducts: biomarkers of exposure**
 - **DNA adducts**

Action highlights

Toxicology studies

- **Chronic carcinogenicity studies (bioassay)**
- **Germ cell toxicity**
- **Neurotoxicity**
 - **Not cited as concern by WHO/FAO**
 - **More information useful**



Action highlights



Epidemiology

- **Power available to detect small risks?**
- **FDA will consider**
 - **Occupational studies**
 - **Prospective cancer studies**
 - **Case-control cancer studies**



Food survey progress

- **About 400 food samples analyzed to date**
- **More than 35 different food types**
- **More testing planned for future**

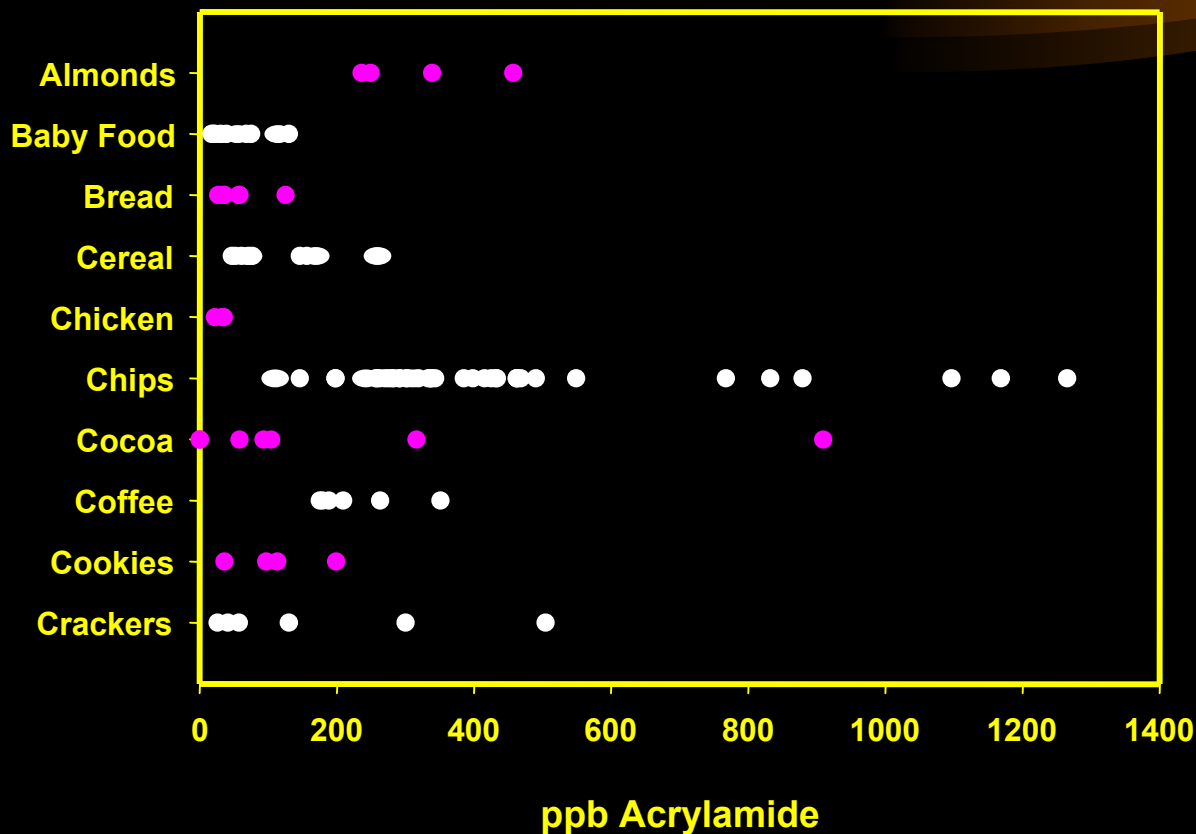


Food survey progress

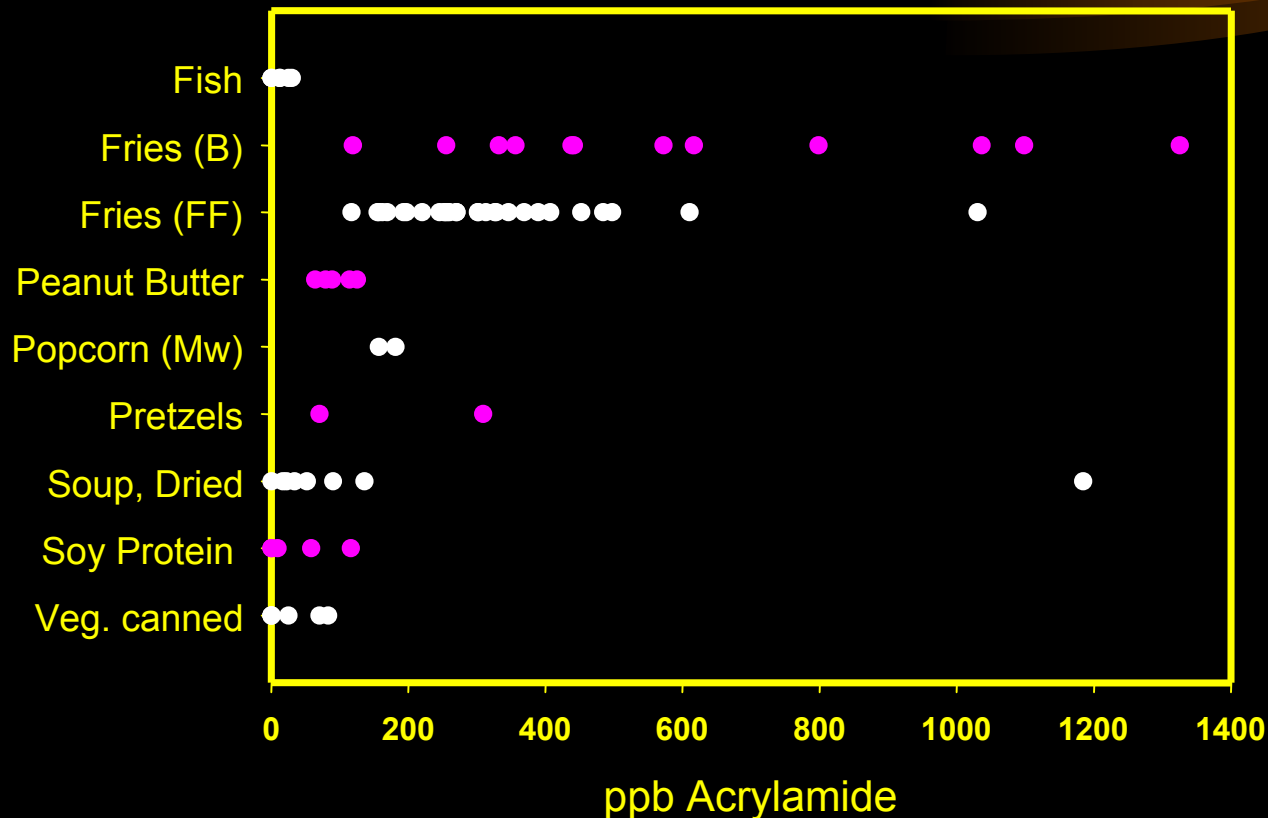
- Some foods have little or no acrylamide, such as infant formula, baby cereal, fish and chicken, and condensed and liquid milk.
- Other foods have acrylamide, but in variable amounts.



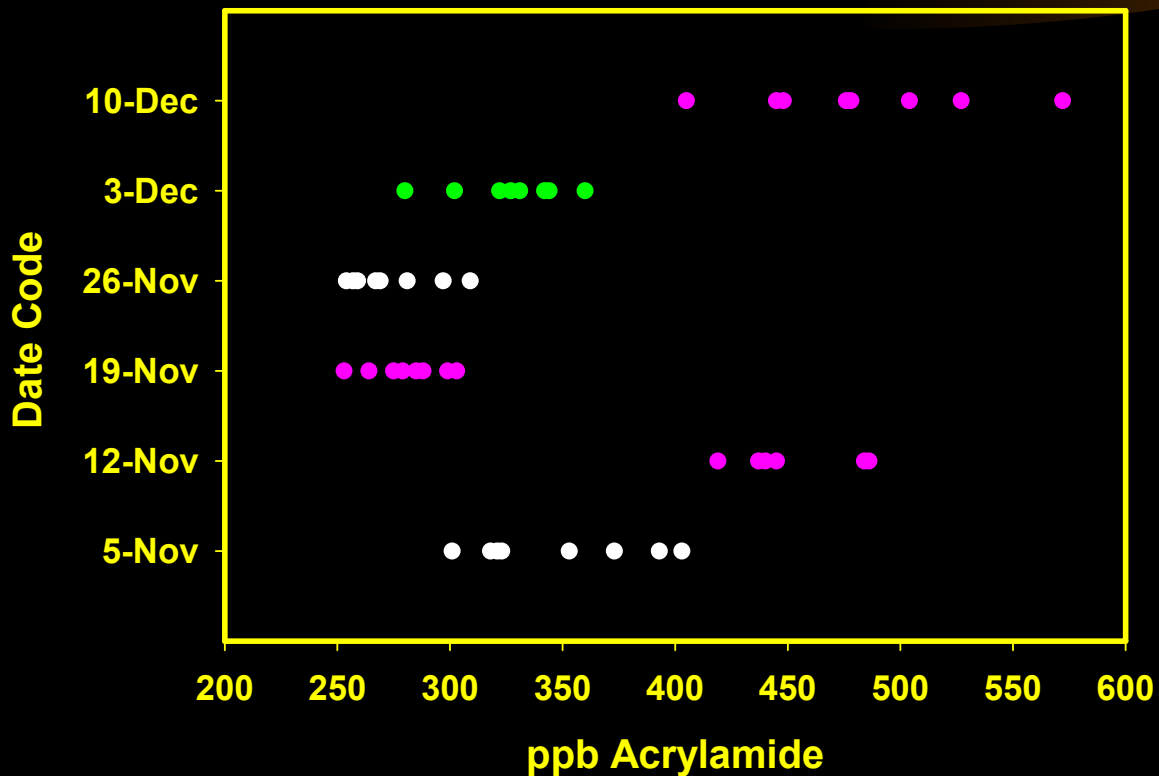
Examples of variability within selected food groups



Examples of variability within selected food groups



Lot to lot variability in potato chips



Formation and reduction strategies

- **FDA, along with academia and industry, is looking at what factors affect acrylamide levels in food.**
- **Strategies suggested to control acrylamide levels in food**
 - **Remove precursors (asparagine, sugars) from food**
 - **Disrupt acrylamide-producing reaction**
 - **Remove formed acrylamide from food**



Factors affecting acrylamide formation

- **Food composition**
 - Amino acids, sugars
 - pH
 - Moisture
- **Processing conditions**
 - Temperature
 - Time

Effect of temperature



160 °C
27 ppb

170 °C
70 ppb

180 °C
326 ppb

Acrylamide levels in potato chips fried for 4 minutes increased with frying oil temperature.

Effect of time



3.5 m
12 ppb

4 m
46 ppb

4.5 m
227 ppb

5 m
973 ppb

Acrylamide levels in potato chips fried at 180 °C increased with frying time.

Consumer cooking and time



0 Minutes
(0 ppb)



15 minutes
(11 ppb)



30 Minutes
(1326 ppb)



45 minutes
(4885 ppb)

Baked (Oil Coating)

Data summary

- FDA has measured acrylamide in a wide range of products.
- Acrylamide was detected in a variety of foods and at a variety of levels.
- In some foods, no acrylamide was detected.



Data summary

- FDA has found variability between food categories and within food categories, as well as between different brands.
- The variability in levels of acrylamide in similar foods suggests that there are ways to make products that will minimize acrylamide formation.



Exposure Assessment of U.S. Consumers to Acrylamide

- Presented at February Food Advisory Committee Meeting
- FDA acrylamide data and three food consumption databases (MRCA 1982-1987, CSFII 1989-1992; CSFII 1994, 1996-1998)



Exposure Assessment of U.S. Consumers to Acrylamide

- Population mean lifetime exposure of 0.32 to 0.48 $\mu\text{g}/\text{kgbw-d}$
- Similar to other calculated mean lifetime exposures
- Eight of the tested food types consistently comprise 83 % of the exposure: restaurant and oven-baked French fries, brewed coffee, breakfast cereal, potato chips, cookies, toast, and soft bread.



Exposure Assessment of U.S. Consumers to Acrylamide

- Each of the eight food types contributes 5 percent or more to total acrylamide exposure.
- No one food accounts for the majority of the mean population acrylamide intake.
- Some foods with lower acrylamide values contribute appreciably to the overall mean population acrylamide intake because they are commonly consumed.



Consumer message

- **FDA's current dietary message for acrylamide is to: "Eat a balanced diet, choosing a variety of foods that are low in trans fat and saturated fat, and rich in high-fiber grains, fruits, and vegetables."**
- **The FDA believes there are not enough scientific data to justify changing the message at this time.**



Consumer message

- **Advice must be carefully constructed so as not to expose consumers to greater risk, e.g.,**
 - Potential for undercooking given advice not to overcook
 - Potential for omitting important staples of the diet



Conclusion

- Acrylamide info at www.cfsan.fda.gov (under Pesticides and Contaminants)
- Today's talk
 - Reviewed Action Plan
 - Reviewed work by FDA on methods, testing, exposure, risk assessment, public outreach and risk communication

